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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/943,443	08/30/2001	Jean-Christophe Audonnet	454313-2220.1	9956

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EXAMINER

CHEN, STACY BROWN

ART UNIT PAPER NUMBER

1648

DATE MAILED: 09/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/943,443

Applicant(s)

AUDONNET ET AL.

Examiner

Stacy B. Chen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 21-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 August 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☒ Certified copies of the priority documents have been received in Application No. 10/232,278.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION*****Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 30, 2006 has been entered. Claims 21-25 are pending and under examination.

***Claims Summary***

The claims as amended are drawn to a method for inducing in a feline host an immunological response against feline immunodeficiency virus comprising administering to a feline host at least one naked plasmid, wherein the plasmid contains nucleic acid molecules having sequences encoding feline immunodeficiency virus env protein, or gag protein, or pro protein, or gag and pro proteins, or env and gag and pro proteins. The plasmid further comprises a cytomegalovirus early promoter. The polynucleotide sequences are expressed *in vivo* in a feline host cell. The method further comprises administering a live whole vaccine against a feline pathogen, or an inactivated whole vaccine against a feline pathogen, or recombinant vaccine against a feline pathogen, or a subunit vaccine against a feline pathogen.

***Response to Amendment***

In view of Applicant's amendments, the following rejections are withdrawn:

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- The rejection of claims 21, 24 and 25 under 35 U.S.C. 102(a) as being anticipated by Wardley *et al.* (WO95/30019, "Wardley") is withdrawn in view of Applicant's amendment. The claims are drawn to a method for inducing in a feline host an immunological response against feline immunodeficiency virus comprising administering to a feline host at least one naked plasmid, wherein the plasmid contains and expresses in vivo in a feline host cell nucleic acid molecules having sequences encoding feline immunodeficiency virus env protein, or gag protein, or pro protein, or gag and pro proteins, or env and gag and pro proteins. Wardley administers a plasmid in a vector. Therefore, Wardley's teachings do not anticipate the instantly claimed invention.
- The rejection of claims 22, 23 and 25 under 35 U.S.C. 103(a) as being unpatentable over Wardley as applied to claims 21, 24 and 25 above, and further in view of Mazzara *et al.* (U.S. Patent 5,804,196, "Mazzara"), is withdrawn in view of Applicant's amendment. Since Wardley does not anticipate the instantly claimed invention, the obviousness rejection is withdrawn.

### ***Claim Rejections - 35 USC § 112***

(*New Rejection*) Claims 21-25 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for inducing a humoral immune response in a feline when administering a naked plasmid construct comprising gp120, does not reasonably provide enablement for inducing a cellular immune response when administering a naked plasmid construct comprising gp120. The specification does not reasonably provide a method of inducing an immune response (humoral or cellular) against FIV when administering a naked

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plasmid construct comprising gag and pro gene in the absence of env. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include, but are not limited to the breadth of the claims, the nature of the invention, the state of the prior art, the level of one of ordinary skill, the level of predictability in the art, the amount of direction provided by the inventor, the existence of working examples; and the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The breadth of the claims encompasses the induction of an immune response (humoral, cellular, or humoral and cellular) against FIV by administering naked plasmid constructs comprising env, gag, pro, gag/pro and env/gag/pro. The nature of the invention is inducing an immune response against FIV in cats, wherein the immunizing agent is a naked DNA that encodes in vivo a protein that will induce the immune response against FIV and thus treat or prevent disease. The state of the art shows that inducing a humoral immune response against FIV env is possible when administering a naked plasmid that encodes env protein. Cuisinier *et al.* (*Vaccine*, 1997, 15(10):1085-1094, "Cuisinier") discloses DNA vaccination using expression vectors carrying FIV structural genes that are studied for their ability to induce an immune response against FIV. Cuisinier vaccinated cats intramuscularly with naked DNA coding for FIV structural proteins envelope, gp120, and nucleocapsid (gag), p10 (page 1086, first column, first full paragraph). The construction of the plasmids pCMV-10 and pCMV-120 is described on

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page 1086, columns 1 and 2, bridging paragraph. Expression of envelope and nucleocapsid proteins was observed *in vivo* after transfection with the pCMV plasmid constructs directly under the control of the CMV promoter (page 1087, second column, "RESULTS" section). As for immune responses to the pCMV plasmid constructs, the pCMV-120 construct induced a humoral immune response, while the pCMV-p10 construct, interestingly, induced no humoral immune response (see Table 1, page 1090, and page 1091, column 2, first full paragraph).

Given the data presented in Cuisinier, there is a low level of predictability for immunizing cats with FIV naked DNA constructs. Applicant has not provided any working examples or guidance that overcome the problem disclosed in Cuisinier's work. Therefore, given the breadth of the claims, the state of the art, and the lack of working examples, it would require undue experimentation to induce a cellular immune response against FIV using a naked DNA plasmid encoding env protein. It would also require undue experimentation to induce a humoral or cellular immune response against FIV using a naked DNA plasmid that does not encode the env protein.

### ***Claims Rejections - 35 USC § 102***

Upon further consideration of the claimed invention and the prior art, the following rejection is set forth. Any inconvenience is regretted. The instantly claimed invention has priority to its parent application, 09/232,278, filed January 15, 1999.

(*New Rejection*) Claims 21 and 24 are rejected under 35 U.S.C. 102(b) as anticipated by Cuisinier *et al.* (*Vaccine*, 1997, 15(10):1085-1094, "Cuisinier"). Cuisinier discloses DNA vaccination using expression vectors carrying FIV structural genes that are studied for their

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ability to induce an immune response against FIV. Cuisinier vaccinated cats intramuscularly with naked DNA coding for FIV structural proteins envelope, gp120, and nucleocapsid (gag), p10 (page 1086, first column, first full paragraph). The construction of the plasmids pCMV-10 and pCMV-120 is described on page 1086, columns 1 and 2, bridging paragraph. Expression of envelope and nucleocapsid proteins was observed *in vivo* after transfection with the pCMV plasmid constructs directly under the control of the CMV promoter (page 1087, second column, "RESULTS" section). As for immune responses to the pCMV plasmid constructs, the pCMV-120 construct induced a humoral immune response, while the pCMV-p10 construct, interestingly, induced no humoral immune response (see Table 1, page 1090, and page 1091, column 2, first full paragraph). In view of Cuisinier's teachings, the subject matter of claims 21 and 24 is anticipated.

### ***Conclusion***


No claim is allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The

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examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

 9/15/06  
STACY B. CHEN  
PRIMARY EXAMINER